54. The process of claim 41 wherein the molecular weight of the hydroxypropylmethylcellulose in the degassed solution is about 410,000.

55. A viscoelastic composition for injection into a human eye, the viscoelastic composition comprising hydroxypropylmethylcellulose in a physiological salt solution,

the hydroxypropylmethylcellulose having an average molecular weight greater than about 375,000 but less than about 420,000 and being present in a concentration from about 2.0% to about 2.5%,

the composition having a viscosity from about 25,000 centipoise to about 40,000 centipoise, being free of particulate matter and gels greater than 0.5 μm in diameter and being pyrogen free and nontoxic.

56. The viscoelastic composition of claim 55 wherein the concentration of the hydroxypropylmethylcellulose is about 2.3%, the average molecular weight of the hydroxypropylmethylcellulose is about 409,800 and the zero shear viscosity of the composition is about 40,000 centipoise. --

REMARKS

By Notice of Allowance and Issue Fee Due dated June 13, 2001, Claims 1-56 of the present application were allowed and the Issue Fee was paid August 9, 2001. Two months later, Applicant was surprised to receive an Office Action withdrawing the case from issue. Specifically, the Office Action recites that Claims 31-56 are withdrawn from consideration, and that Claims 1-30 are rejected under 35 U.S.C. §103. For the reasons stated below, Applicant respectfully submits that the withdrawal of the present application from issue is both untimely and inappropriate.

37 C.F.R. §1.313(b) provides:

Once the Issue Fee has been paid, the Office will not withdraw the application from issue at its own initiative for any reason except:

(1) A mistake on the part of the Office;

(2) A violation of §1.56 or illegality in the application;

(3) Unpatentability of one or more claims; or

(4) For interference.

None of the foregoing criteria have been asserted in the present Office Action as a basis for the withdrawal of the case from issue. The Office Action recites no request to the Technology Center Director to withdraw the present case from issue, nor has Applicant received a "Notice of Withdrawal" under 37 C.F.R. §1.313(b) signed by such Director. See MPEP §§1002.02(c)(19) and 1308. Nor did the Office Action contain a Form 13.05 paragraph advising Applicant of its options concerning the already paid issue fee. See MPEP §1308.03. Similarly, the Office Action contains no form paragraph 13.04 prefatory to an enumeration of reasons for unpatentability under 37 C.F.R.§1.313(b).

In view of the failure by the Patent Office to comply with the procedures governing the withdrawal of a case from issue subsequent to the payment of issue fee, Applicant respectfully submits that the present Office Action, which purports to withdraw the case from issue, should be deemed ineffective, and the case should be allowed to issue in due course.

In the event the numerous procedural deficiencies relating to the outstanding withdrawal from issuance are deemed to be immaterial, Applicant offers the following remarks directed to the arguments contained in the present Office Action. Claims 1-56 are pending in the present application. By her Office Action dated November 9, 2001, the Examiner has rejected Claims 1-30 under 35 U.S.C. §103 and has withdrawn from consideration Claims 31-56. By the present amendment, Claims 31-56 are properly restored.

With respect to the Examiner's §103 rejection of Claims 1-30, Applicant respectfully traverses. The Examiner has cited Hazariwala et al., and Fechner. As discussed at length in previous communications, neither of these references disclose or suggest the high viscosity, high molecular weight hydroxypropylmethylcellulose solutions of the present invention. Rather, the hydroxypropylmethylcellulose described in these prior art references is without exception low molecular weight, low viscosity material that lacks sufficient viscosity to be practically useful as a visco-surgical tool. The Examiner asserts that Applicant has presented "no evidence to establish the unexpected or unobvious nature of the claimed invention." To the contrary, in response to the Examiner's prior assertion of these same prior art references, Applicants submitted multiple declarations and articles establishing the unexpected attributes of the hydroxypropylmethylcellulose solutions of the present invention. This evidence, was submitted in Applicant's Response and Amendment

of September 19, 2000, and its Supplemental Response of October 12, 2000, filed with respect to Application Serial No. 08/870,199. As the present application is a continued prosecution application of Application Serial No. 08/870,199, the foregoing evidence is of record in the present case. Moreover, in view of that previously submitted evidence, the Examiner indicated that the bases for her rejection had been fully overcome and actually allowed all thirty claims. Applicant urges the Examiner, therefore to review the substantial evidence of record distinguishing the hydroxypropylmethylcellulose solutions of the present invention from the cited art. If not previously noted, it should be appreciated that nothing in the cited references discloses or suggests a blend of different molecular weight hydroxypropylmethylcellulose materials to achieve a material having the properties of the composition presently claimed. See Claims 6-11 and 15-18. Applicant has therefore satisfied its obligations to make a prima facia showing of nonobviousness over the cited art. For all of the foregoing reasons, favorable reconsideration of all rejected claims is respectfully requested.

The Examiner has further asserted that the reason for withdrawing the application from issue is that the reissue claims, which are said to be "both narrowed and broadened," are thought to be violative of the recapture rule. Understanding this to be a basis for rejection of Claims 1-30, Applicant traverses. The recapture rule precludes an applicant from securing, through a broadening reissue, subject matter that was surrendered during the prosecution of the parent application. Hester Industries Inc. v. Stein Inc., 46 USPQ2d 1641, 1648 (Fed. Cir. 1998) citing In re Clement, 45 USPQ2d 1161, 1164 (Fed. Cir. 1997). Classically, the recapture rule comes into play when claims that have been cancelled or amended during prosecution in order to overcome prior art are reasserted in a reissue application. In those instances, if it is determined that the claims were cancelled or amended to secure allowance of narrower claims (and the original claims were not reasserted in a continuation application), then such cancellation/amendment constitutes evidence that the subject matter of the cancelled claim has been surrendered. Under those circumstances, it would be impermissible to allow an applicant to attempt to reclaim or recapture the surrendered subject matter through a reissue application. The foregoing classical fact pattern is not present in this case. Rather, the Examiner is asserting that arguments made during the prosecution, without any accompanying amendments, constitute a surrender of subject matter. Applicant acknowledges the finding in Hester that under certain circumstances, argument alone can be sufficient to constitute such a surrender. Those circumstances, however, are not present in this case.

In Hester, the reissue applicant attempted to delete from the reissue claims two limitations, both of which had been argued in the parent case prosecution as being critical to distinguish the invention over the prior art. Under those circumstances, the court found that the applicant's "repeated arguments" in the parent case prosecution constituted "an admission...that these limitations were necessary to overcome the prior art." Id. at 1649. Thus, the court found that the deleted limitations were the "primary bases indicated for patentability." Id. Moreoever, the court in Hester did not find any offsetting narrowing of the reissue claims that might afford an exception to the recapture rule.

The facts and holding of Hester are inapposite to the present case. In her Office Action, it is stated, "[T]he Examiner accepted [the 0.5μm limitation] as a defining limitation based on at least one of the affidavits submitted to obtain allowance of the claims." There is, however, no indication in the record of such reliance by the Examiner. Nor does the Office Action specify the nature of the alleged argument concerning the 0.5μm limitation or even identify the declaration which contains it. The undersigned has reviewed the following four declarations submitted during prosecution of the applications which resulted in the issuance of U.S. Patent No. 5,422,376 to which this reissue application is directed:

Bradford C. Webb Declaration dated March 10, 1994;
Richard G. Livernois Declaration dated March 10, 1994;
John D. Hunkeler Declaration dated March, 1994; and
Bradford C. Webb Declaration dated July 31, 1994

Each of the foregoing Declarations has been submitted in the present reissue prosecution. Prior to the withdrawal of the issuance of the present application, there had been no suggestion that any of these four declarations established "criticality" relative to the 0.5μm limitation. This is understandable in view of the fact that collectively, the four declarations refer to the viscosity and/or molecular weight characteristics of the solutions of the present invention approximately 15 times, whereas "0.5μm" is mentioned only once. That reference is by Dr. Hunkeler who states at paragraph 14 of his Declaration, "I have been informed that the process claimed in the subject patent application removes all particulate matter greater than 0.5μ and all dissolved gases from Cellugel™ materials. In my experience, because of this unique process, Cellugel™ materials are always very clear." At best, this demonstrates that the 0.5μm filtration will result in a preferred embodiment, i.e. one that exhibits superior clarity. It does not, however, constitute any evidence that the 0.5μm limitation was

considered to be critical to the presently claimed invention. Consequently, the Examiner's characterization of the foregoing statement as a "defining limitation" appears to be unfounded.

In the classical case involving claim amendments during prosecution, it is established that "the recapture rule does not apply in the absence of evidence that the amendment was an admission that the scope of the claim was not patentable." Hester, 46 USPQ2d at 1648, citing Clements, 45 USPQ2d at 1164. Conversely, in the more difficult case, where recapture is being argued based strictly on argument made during prosecution, the rule cannot apply in the absence of evidence that a particular claim limitation was essential to distinguish over the prior art. In this case, the Examiner would need to present evidence that without the 0.5µm limitation the applicant would have considered the invention to be unpatentable. This is simply not the case. To the contrary, the key characteristics of the hydroxypropylmethylcellulose solutions of the present invention relate to viscosity and molecular weight. Admittedly, filtration of the inventive solutions through a 0.5µm filter will yield a preferred embodiment. Nothing in the record, however, states that such a filtration step (or absence of particles of that size) by itself is critical. Nor is there any suggestion that the high viscosity, high molecular weight hydroxypropylmethylcellulose solutions of the present invention would not be patentable without that limitation. Indeed, claims in the corresponding European patent application were recently allowed to a "hydroxypropylmethylcellulose solution free of harmful particulate material, said viscoelastic solution having a zero shear viscosity in excess of 15,000 cps [and] an average molecular weight in excess of 250,000 Daltons..." A copy of the 30 allowed claims is attached hereto for informational purposes only. Clearly the 0.5µ limitation has not been considered essential for patentability. In summary, the recapture rule is not applicable to the present case.

Assuming solely for the sake of argument that the broadening aspect of the present reissued claims would otherwise be violative of the recapture rule, the corresponding narrowing aspect of the present claims is sufficient to avoid application of the rule. Specifically, the 0.5µm limitation has not simply been removed. It has been replaced with another limitation that ensures utility of the claimed invention and provides the applicant the "scope of protection to which he is rightfully entitled." Hester, 46 USPQ2d at 1650. The applicant notes that further limitations have been included to impose the viscosity limitations in claims 13 and 27. Once again, these offsetting narrowing limitations provide justification

for an exception to the recapture rule in accordance with the principle articulated in Ball Corp. v. United States, 221 USPQ 289 (Fed. Cir. 1984). In summary, applicant respectfully submits that application of the recapture rule based strictly upon argument made during prosecution in the parent prosecution should only be made in instances where the subject matter has been unmistakably surrendered and where that subject matter is undeniably critical to the patentability of the claims issued in the parent application. The present facts simply do not warrant application of the recapture rule, and the Examiner's favorable reconsideration of its withdrawal of the case from issuance or allowance of all pending claims is therefore requested.

Regarding the withdrawal from consideration of claims 31-56, applicant has, in accordance with the Examiner's request, resubmitted those claims as new claims through the present amendment. Applicant's intent in submitting these claims in columnar format with its Response and Amendment dated September 18, 2000, was simply to demonstrate to the Examiner that these claims were, with the exception of claim numbering, identical to the issued claims of the parent patent, U.S. Patent No. 5,422,376. Applicant has made every effort to ensure that the claims of the present amendment are properly transcribed and represent the previously issued claims. Consequently, no new matter has been added with respect to the present amendment. Applicant respectfully requests entry and allowance of these new claims.

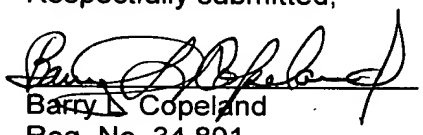
The Examiner has indicated that a supplemental declaration is required for any amendments made during the prosecution, citing MPEP § 1414.01. Applicant respectfully disagrees. Such additional declaration is only necessary "if additional defects or errors are corrected in the reissue after the filing of the application and the original reissue oath or declaration." MPEP §1414.01. No additional defects or errors are being asserted in the present case and the added claims merely represent the claims previously issued in the parent patent. Applicant believes all errors were properly identified in the original reissue oath/declaration.

Finally, concerning fees, payment of the fees associated with the independent claims contained in the newly added claims was previously authorized under applicant's Response and Amendment dated September 19, 2000. Presumably these fees have been withdrawn from Applicant's Deposit Account. Regarding the issue fee already paid by applicant, applicant elects to wait until this case is found to be allowable with the intention that the previously paid issue fee be applied at that time.

The foregoing remarks are intended to be fully responsive to the Examiner's November 9, 2001, Office Action. In the event, however, the Examiner believes this response is lacking in any respect, or requires any further information, she is urged to call the undersigned to resolve any remaining issues.

Respectfully submitted,

Date: May 9, 2002

By: 

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VERSION WITH MARKINGS TO SHOW CHANGES MADE

IN THE CLAIMS

Please add the following new claims 31-56:

31. An improved composition for physiological applications, said composition containing hydroxypropylmethylcellulose in a physiological salt solution, the improvement comprising a hydroxypropylmethylcellulose solution free of particulate matter and gels greater than 0.5 µm in diameter, said viscoelastic solution having a zero shear viscosity in excess of 15,000 cps, an average molecular weight in excess of 250,000 Daltons and being pyrogen free and non-toxic when a therapeutically effective amount of said solution is injected into a human body.

32. The improved composition of claim 31 wherein said composition being pyrogen free and non-toxic when a therapeutically effective amount of the solution is injected into a human eye.

33. The viscoelastic solution of claim 32 wherein the hydroxypropylmethylcellulose is present in a concentration from about 2.0% to about 2.5%.

34. The viscoelastic solution of claim 32 wherein the viscosity of the solution is from about 25,000 centipoise to about 40,000 centipoise.

35. The viscoelastic solution of claim 32 wherein the average molecular weight of the hydroxypropylmethylcellulose is greater than about 375,000 but less than 420,000.

36. The viscoelastic solution of claim 32 prepared from a blend of a first hydroxypropylmethylcellulose having a first molecular weight and a second hydroxypropylmethylcellulose having a greater molecular weight, the blend being processed to produce the particulate free, pyrogen free, and non-toxic solution.

37. The viscoelastic solution of claim 36 wherein the blend is processed by filtration, redissolving and removal of low molecular weight material, mid-process autoclaving and removal of dissolved gases.

38. The viscoelastic solution of claim 37 wherein the hydroxypropylmethylcellulose in the viscoelastic solution after processing has an average molecular weight greater than the average molecular weight of the first hydroxypropylmethylcellulose or the second hydroxypropylmethylcellulose.

39. The viscoelastic solution of claim 36 wherein the first hydroxypropylmethylcellulose has an average molecular weight of about 85,000 and the second hydroxypropylmethylcellulose has an average molecular weight of about 220,000.

40. The viscoelastic solution of claim 38 wherein the average molecular weight of the hydroxypropylmethylcellulose after processing is greater than 375,000 but less than 420,000.

D1 cont

41. The viscoelastic solution of claim 36 having a hydroxypropylmethylcellulose concentration of about 2.3%.

42. The viscoelastic solution of claim 35 wherein the hydroxypropylmethylcellulose has an average molecular weight of about 410,000.

43. A process for preparing a viscoelastic solution of hydroxypropylmethylcellulose in a physiological salt solution, the composition being free of particulate material and gels greater than 0.5 μm in diameter and being pyrogen free and non-toxic when a therapeutically effective amount of said solution is injected into a human eye, the process comprising the steps of:

a) dispersing the hydroxypropylmethylcellulose in the salt solution to form a suspension,

b) heating the suspension of step (a) to about 95° C, allowing any undissolved material to settle and discarding the supernatant liquid above the undissolved material,

c) resuspending the undissolved material to form a second suspension of hydroxypropylmethylcellulose and heating the second suspension to form a thick gel,

d) filtering the gel through a series of filters, the series including a final filter having 0.5μm openings to form a clean solution,

e) autoclaving the clean solution,

f) cooling the autoclaved clean solution and filtering the cooled solution, and

g) degassing the filtered cooled solution.

43 cont.

44. The process of claim 43 wherein the physiological salt solution has a pH of about 8.7 and contains NaCl, KCl, $CaCl_2.2H_2O$, $MgCl.6H_2O$, $NaC_2H_3O_2.3H_2,O$, $Na_3C_6HO_7.2H_2O$.

45. The process of claim 43 wherein the hydroxypropylmethylcellulose dispersed in the aqueous salt solution is a blend of a first hydroxypropylmethylcellulose having a first molecular weight and a second hydroxypropylmethylcellulose having a higher molecular weight.

46. The process of claim 45 wherein the first hydroxypropylmethylcellulose has a molecular weight of about 85,000 Daltons and the second hydroxypropylmethylcellulose has a molecular weight of about 220,000 Daltons.

47. The process of claim 45 wherein the weight of the first hydroxypropylmethylcellulose in the suspension is about the weight of the second hydroxypropylmethylcellulose.

48. The process of claim 45 wherein the hydroxypropylmethylcellulose in the suspension is about 3% by weight.

49. The process of claim 43 wherein the concentration of the hydroxypropylmethylcellulose in the degassed solution is from about 2.0% to about 2.5%.

50. The process of claim 43 wherein the concentration of the hydroxypropylmethylcellulose in the degassed solution is about 2.3%.

51. The process of claim 43 wherein the viscosity of the degassed solution is from about 25,000 centipoise to about 40,000 centipoise.

52. The process of claim 43 wherein the viscosity of the degassed solution is about 40,000 centipoise.

D1 cont.

53. The process of claim 43 wherein the molecular weight of the hydroxypropylmethylcellulose in the degassed solution is greater than about 375,000 but less than about 420,000.

54. The process of claim 41 wherein the molecular weight of the hydroxypropylmethylcellulose in the degassed solution is about 410,000.

55. A viscoelastic composition for injection into a human eye, the viscoelastic composition comprising hydroxypropylmethylcellulose in a physiological salt solution,

the hydroxypropylmethylcellulose having an average molecular weight greater than about 375,000 but less than about 420,000 and being present in a concentration from about 2.0% to about 2.5%,

the composition having a viscosity from about 25,000 centipoise to about 40,000 centipoise, being free of particulate matter and gels greater than 0.5 μm in diameter and being pyrogen free and nontoxic.

56. The viscoelastic composition of claim 55 wherein the concentration of the hydroxypropylmethylcellulose is about 2.3%, the average molecular weight of the hydroxypropylmethylcellulose is about 409,800 and the zero shear viscosity of the composition is about 40,000 centipoise.

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